Utah Department of Health

CLINICAL LABORATORY BULLETIN February 2008

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING

No new employees!

NOTEWORTHY

✓ ***Mycobacteria nebraskense*:** This recently identified species was causing fatal lung infections in cancer patients at Nebraska Medical Center. Persistent microbiologists at the medical center discovered the isolate had distinct sequence characteristics in the 16S rRNA gene. It contained a unique mycolic acid profile. The ITS-1 region target was different from other mycobacterium as were some phenotypic characteristics.

The new species is closely related to *M. kansasii and M. avium* in appearance, growth patterns and the disease it causes. Researchers hope to have a direct test available soon to detect the organism's unique genetic sequence.

✓ **Transfusion reaction – who makes the call?:** Krishna Oza, MD in the Department of Pathology for the University of Arkansas for Medical Sciences answered that question for MLO in October, 2007. She answered the question by quoting from the American Association of Blood Banks Technical Manual, "All personnel involved in the ordering and administering transfusion must be able to recognize a transfusion reaction so that appropriate actions can be taken promptly."

Dr. Oza makes recommendations for facilities to ensure the hospital policy allows even lab personnel to determine a reaction work-up is necessary. She further states the only patient symptom that, by itself, does not require a reaction work-up is rash (urticaria). For rashes the transfusion should be stopped, anti-histamines given, and with symptom resolution, the transfusion may be restarted slowly.

Just assume any other symptoms are a transfusion reaction until proven innocent. It is better to do a work-up than have the patient expire. Dr. Oza's facility considers a 2°F temperature increase (as long as it brings the patient to at least 100°F) enough to stop the transfusion and begin the work–up.

"Once a particular policy is agreed upon and adopted by an institution, however, strict conformance with the policy should be required for the safety of the patient."

✓ **Using the correct blood collection tube:** CLIA requires the source of a sample be on the sample itself (not just on the requisition) if

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applicable. A blood sample is blood, so that rule doesn't apply, right? Maybe!

Suppose a physician office sends a blood sample to their associated hospital lab. The lab performs some of the tests requested, but sends others to a large reference lab. When the sample is separated into a transport tube, serum looks just like plasma! Different test methods can require different samples. For example, certain esoteric tests, such as factor VIII assay, may require citrate plasma – not EDTA plasma. Even serum can be problematic. Some assays have found gel separator tubes can interfere with test accuracy.

If you are the facility that separates the sample from the original tube, make sure the type of collection tube is reflected on the label of the "specimen" being sent for testing.

✓ **Laboratory jargon:** Joint Commission for hospital accreditation has an official "Do Not Use" list of abbreviations, acronyms and symbols. The 15-item list seems to be for nursing and pharmacy with items like QD and MS. They also have a list of recommended additions to the list such as abbreviated drug names, cc and μ, >, <, @. For information on why these items cause confusion and even patient harm, check their website www.jointcommission.org.

In the clinical laboratory we have our own problem abbreviations. Does PT mean patient, prothrombin time or proficiency testing? Does GC mean gonococcus or gas chromatography? Does WIC mean Western Integrity Center or Women, Infants and Children clinic? Put your staff to work coming up with other things we abbreviate that have multiple meanings to our customers. Then eliminate these abbreviations from your written communication.

✓ **Multipotent progenitor cell:** In the 12/15/07 issue of *Medical News Today* researchers announced the discovery of a human blood cell coming directly from the blood-forming stem cell in bone marrow. The cell is known in mice, but this is the first reported isolation from human blood. It is hoped this discovery will lead to leukemia and other blood disorder treatments.

✓ **Changing blood gas analyzers = changing anti-coagulants:** "The use of heparin in preparing samples for blood-gas analysis" is the October 2007 MLO cover story. The author, Chris Higgins, MS, states when blood gas analyzers measured samples for gases (pCO2 and O2) and pH only, using heparinized blood was okay. With newer analyzers adding hemoglobin, electrolytes and finally ionized calcium, the game plan has changed. Mr. Higgins points out two potential problems with heparin – simple dilution of the sample and direct interference with the testing.

For blood gas tests without hematology analytes, electrolytes or ionized calcium, the heparin concentration should be less than 200 IU/mL blood and not dilute the sample more than 5%. Adding electrolytes means lithium heparin must be used instead of sodium heparin. Adding ionized calcium means the heparin should be lyophilized in the syringe and its concentration should not exceed 10 IU/mL blood. Alternately, a specialized heparin (such as zinc-lithium heparinate blend) that eliminates heparin's calcium binding effect may be used.

For the more information, refer to the original article at www.bloodgas.org.

✓ **Hematocrit variation – additional information:** In November's Lab Bulletin I listed some factors that affect accurate hematocrit (hct) testing. Daniel M. Baer, MD added some to that list when he responded to a question in the October 2007 MLO.

The same sample repeated on the same instrument will vary as much +/- 3.94%. For a

hct of 42, the 95% confidence range would be 40.3% to 43.7%. This normal variation can be extended by posture changes. A patient who has been lying down and then sits up can have a hct drop from 7% to 15% depending on the study you read. Samples drawn in the morning can be more than 5% higher than those drawn later in the day. Tourniquets left on more than one minute also affect results.

Armed with these facts, you can help clinicians understand variability in their patient is probably not "lab error".

✓ **Update DOT regulations - shipping human samples by private courier:** Federal Department of Transportation regulations were revised 10/1/07 (49 CFR 173.134). The definition for Category 6.2 (Infectious substance) B is "An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes." (a)(1)(ii)

In (b)(10) is listed an exception for private couriers. "A Division 6.2 material, other than a Category A infectious substance, contained in a patient sample being transported for research, prevention, or a biological product, when such materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials." **Note this section seems to apply to transporting test specimens not suspected of being dangerous (such as testing for anthrax, *Brucella* or other select agents) to a reference lab. It also states the vehicle must be used EXCULSIVELY for transporting samples. If a contract carrier uses their own car – all Category B packaging rules apply. If sending a sample to rule out a select agent – all Category A packaging rules apply.**

You can access the entire DOT regulations at www.federalregister.gov.

✓ **Rabies in Utah:** The Utah Public Health Laboratories (UPHL) tests numerous animal brain tissue samples each year for rabies. Samples are sent when human exposure is known or suspected. Unfortunately, this "old" disease is still with us. Since 1987 there have been only 41 deaths in this country from US acquired rabies. The disease is treatable when detected early. It is just as important to know a sample is negative (treatment can be stopped) as it is to know the sample is rabies positive.

Utah is seeing a small but steady rise in the number of examinations as well as the number of positive samples.

2004 = 590 exams, 8 positive (8 bats)
2005 = 546 exams, 16 positive (16 bats)
2006 = 585 exams, 18 positive (17 bats, 1 fox)
2007 = 654 exams, 20 positive (20 bats)

✓ **Cutting laboratory costs:** COLA's January/February '08 issue of Insights has an article titled "Financial 'Check-Up': Maximizing Revenue in the Laboratory". A private consultant, Tim Dumas, gave good advice on ways to improve productivity and cut cost. One cost saving tip was "Consider using off-brand reagents. Ask your vendor about this option." There is nothing wrong with using a "generic" as long as your instrument's manufacturer states in writing it is okay. You still should validate the reagents perform as well over the entire range of patient test values as does the manufacturer's brand. Even if the manufacturer does not approve an "off" brand, you may still use it providing you do a complete validation including reproducibility, accuracy, sensitivity, specificity, and interfering substance checks. Take into account the cost of the validation in time and reagents before you make the switch.

One excellent suggestion in the article is "For best financial 'health', schedule a 'check-up' at least one per year for maximized revenue."

"Take risks. You can't fall off the bottom."
Barbara Procter

Feature

Clinical Laboratory Improvement Amendments (CLIA)

How to Obtain a CLIA Certificate Brochure #5

When is a CLIA certificate required?

Do I Need To Have A CLIA Certificate?

CLIA requires all facilities that perform even one test, including waived tests, on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

What Are the Different Types of CLIA Certificates and How Long Are They Effective?

All types of certificates are effective for two years and the different types of certificates are:

- **Certificate of Waiver (COW):**

Issued to a laboratory that performs only waived tests.

- **Certificate for Provider Performed Microscopy (PPM) procedures:**

Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.

- **Certificate of Registration:**

Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.

- **Certificate of Compliance (COC)**:

Issued to a laboratory once the State Department of Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

- **Certificate of Accreditation (COA):**

Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

There are six CMS-approved accreditation organizations:

- AABB
- American Osteopathic Association (AOA)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Contact information for the above CMS-approved accreditation organizations is available on the CMS CLIA web site at www.cms.hhs.gov/clia. If you apply for accreditation by one of the CMS-approved accreditation organizations, you must also apply to CMS for a COA concurrently.

What Is A Waived Test?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result". The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

How Can I Find A List Of Waived Tests?

For a list of waived tests sorted by analyte name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

Where Can I Find Information About Tests Categorized As Nonwaived (I.E., Moderate and/or High Complexity)?

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity), refer to the lists of tests online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.
You may also contact the local survey agency at your State Health Department for categorization information concerning tests that you may be performing in your laboratory. A list of State Agency addresses, phone numbers and contact persons is available online under the heading State Survey Agencies (CLIA Contact List) at the CMS CLIA website. If you do not have online access or have questions concerning certification, you may contact the CMS CLIA Central Office at 410-786-3531 for the address and phone number of your local State Agency.

How Do I Apply For A CLIA Certificate?

The CLIA application (Form CMS-116) is available online at the CMS CLIA website located at the end of this brochure. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located. This information is available online or you may contact the CMS CLIA Central Office.

Is There Any Type Of Laboratory Testing That Is Not Subject To A CLIA Certificate?

Yes, there are some testing exceptions that do not require CLIA certification.

The following **exceptions to CLIA certification** apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or
- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

Are There Any States That Exempt Me From Having To Apply For A CLIA Certificate?

Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the

New York State Agency concerning your need for a CLIA certificate.

If I Have More Than One Laboratory Location, Do I Need A CLIA Certificate For Each Location?

You will need a CLIA certificate for **each** location where you perform testing **unless** you qualify for one of the exceptions listed below.

- Laboratories that are not at a fixed location; that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing, may file a single application.
- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your State Agency if you have questions or you are filing a single application for more than one testing site.

What Kind Of Fees Do I Have To Pay To CMS For A CLIA Certificate?

If you apply for COW or a PPM certificate, you will pay a minimal certificate fee every two years. There are no registration or compliance fees.

If you apply for a COC, you will pay a one time minimal registration fee that covers the cost of the CLIA enrollment in addition to a compliance fee that covers the cost of the initial inspection by the State Agency. CMS will send you a Certificate of Registration. Once compliance has been determined by your inspection, you will pay a certificate fee to CMS and CMS will send you a COC. A two-year certificate cycle is then established, and you will pay a certificate fee and a compliance fee every two years. CMS will send you a COC as long as your laboratory is in compliance.

If you apply for a COA, you will pay a minimal registration fee that covers the cost of the CLIA enrollment. Once CMS receives verification from the accreditation organization that you have selected, you will pay a certificate fee and validation fee to CMS and CMS will send you a COA. A two year certificate cycle is then established and you will pay a certificate fee and a validation fee every two years. CMS will send you a COA as long as your laboratory remains compliant. You will pay survey and any other fees to the accreditation organization.

You can obtain more information concerning the amount of certificate fees from the CMS CLIA website under "CLIA Certificate Fee Schedule" or from your State Agency. For information concerning compliance (survey) fees, you may contact your State Agency or accreditation organization. These fees are based on the number and types of testing you perform and must cover the cost of the CLIA program because CLIA is entirely user fee funded.

Will I Receive An Identifying CLIA Number?

You will receive a ten-digit number on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

When Can I Begin Testing?

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate containing your CLIA number. However, you need to check with your State Agency since some states have additional requirements.

Will My Laboratory Receive A CMS Survey?

Laboratories that have a COW or PPM certificate are not subject to routine surveys. However, CMS is currently conducting a

project whereby a small percentage of laboratories that perform only waived testing may receive an educational visit. These visits provide helpful information to staff to help assure the quality of testing and have been extremely well received.

If your laboratory performs any nonwaived testing, the laboratory may have either a COC or COA. All laboratories with either of these certificate types must meet all nonwaived testing requirements and are subject to biennial surveys, by CMS or a CMS agent (such as a surveyor from the State Agency) or by a CMS-approved accreditation organization, if the laboratory is accredited. COA laboratories must also meet the requirements of their accreditation organization.

Additionally, a limited percentage of laboratories with a COA will receive a validation survey by CMS or a CMS agent. This is a survey performed by CMS or a CMS agent to evaluate the results of the most recent survey performed by an accreditation organization.

NOTE: If CMS or the State Agency receives a complaint against your laboratory, you may receive an unannounced on site survey, even though you only perform waived tests or PPM procedures.

If I Have A Certificate For PPM Procedures, A Certificate Of Registration, A COA Or A COC, Can I Also Perform Waived Tests?

Yes, these certificates permit laboratories to also perform waived tests.

If I Have A COA OR A COC, Can I Also Perform PPM Procedures?

Yes, these certificates permit laboratories to perform PPM procedures as well as waived tests. The certificate you obtain should be for the highest (most complex) category of testing you perform.

Do I Need To Notify Anyone If I Made Any Changes In My Laboratory?

For **all** types of CLIA certification, you must notify the State Agency or your accreditation organization within 30 days of any changes in:

- Ownership
- Name
- Location
- Director
- Technical supervisor (for high complexity testing only)

If you perform only waived tests and wish to add PPM procedures or other nonwaived (moderate or high complexity) testing to your menu, you must reapply for the appropriate certificate using the same form (Form CMS-116) you used for your initial CLIA certification. However, you cannot begin nonwaived testing until you have paid the appropriate fee, and have received the appropriate certificate.

If you perform PPM procedures and wish to add other nonwaived (moderate or high complexity) testing, you must first apply for the appropriate certificate.

If you have a COC or COA and wish to add tests categorized under a different laboratory specialty or subspecialty than those on your current certificate or that employ a different test method from those you are already performing, you must notify the State Agency or the accreditation organization of the new testing.

If I Have Any Questions About My Certificate Or Changes In My Test Menu, Who Should I Contact?

You should contact the State Agency where your laboratory is located. You can find this information as well as other information about CLIA at www.cms.hhs.gov/clia or you may contact the CMS CLIA Central Office at 410-786-3531.

Where Can I Find Additional Information And Guidance?

Refer to the "The State Operations Manual", Appendix C – Interpretive Guidelines (CMS Publication 7) available on the CMS website at: www.cms.hhs.gov/clia.

Links to other laboratory-related resources can be found at these websites:
CDC: www.phppo.cdc.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html

CLIA BITS

ADDITIONAL WAIVED TESTS:

° BinaxNOW Influenza A & B
° Jant Pharmacal Accutest *H. pylori* Rapid Test Device and Value + Mono
° Quest Diagnostic Incorporated Express Results Integrated Multi-Drug Screen Cup
° Stanbio Rely Mono Rapid Test
° Abbott Diagnostics Signify ER Drug Screen
° Accutech CholesTrak HDL Cholesterol Home Test
° BTNX Inc. Rapid Response *H. pylori* Whole Blood Rapid Test Device; Multi-Drug One Step Screen Test Panel (Urine); and Know Multi-Drug One Step Screen Test Panel (Urine)
° Diagnostic Test Group Clarity *H. pylori* Rapid Test Device
° Becton Dickinson BD Chek Group A Strep
° Phamatech At Home 12 Drug Test (Model 9308A and 9308T)
° Quidel QuickVue RSV
° Henry Schein One Step + Mononucleosis Rapid Test Device (Whole Blood)

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New HCPCS 2008 CLIA Waived Codes

82310QW Total Calcium
82565QW Creatinine
83655QW Lead
89321QW Sperm presence & motility

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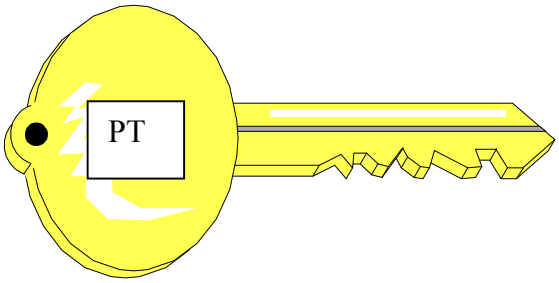
The revised CLIA application (CMS 116 form) dated 10/07 is available on the website www.cms.hhs.gov/clia. Please delete old versions you may have as the updated form asks for some things not previously requested. Some items have been deleted, and some reorganized.

Equals "1 million microphones: 1 megaphone"

Quality Assessment Spotlight

Staff noticed a problem in specimen collection. Several blood spots were not collected correctly and could not be used for testing. Quality assessment tracking showed a few providers consistently having difficulty. The lab produced a video showing how the pre-analytic collection problems adversely affected the patient's test results. Follow up monitoring showed fewer rejected samples and customers were happier.

Kudos Melody Campbell, AAT Deficiency Detection Center



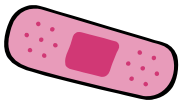
What are your evaluations trying to tell you?

Check the first evaluation report each year to make certain you are being compared with other laboratories using the same method you use. Proficiency test providers may change their forms each year to better capture federally required information. You may have to tell them your method and reagent combination for each event There could be a substantial bias for some tests if you are graded against "all methods".

Make certain you compare your results against the mean (average of everyone using your method) over the past 3 or 4 events. Are you drifting higher or lower? This is called a **"trend"**. Discovering the cause of a trend can prevent future failures.

Was there a sudden **shift** in your results? Last time you were close to the mean, now your results are all very close to the maximum (or minimum). Again this signals a problem that needs fixing. Maybe you need an additional calibration verification or a special instrument cleaning.

Are your normal results close to the mean, but you are very high (or low) with samples that represent abnormal patient results? Talk with the manufacturer about potential problems. Each of these problems may signal a possible error with patient samples. Be certain the clinician has the most accurate result possible to adequately care for the patient.



SAFETY

BD MGIT Tubes

BD sent a safety alert to all MGIT customers in January 2008. Some users reported receiving cracked tubes. The company cautions users to check the tubes before adding patient samples. The cautions they provided are important to follow for any sample collection, processing or testing device.

*Examine clean tubes that are dropped before use for damage.

*Discard damaged tubes.

*If tubes break after the sample is added, follow standard spill clean up procedures. Aerosols may contain infectious organisms.

*Remember any sample may contain infectious bacteria, fungi or virus. Treat every sample as if it contained Hepatitis B. (CDC's Standard Precautions)

*Dispose of all sample and testing supplies in the appropriate biohazard containers and autoclave or have a disposal company pick them up.

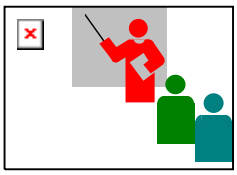
Don't take chances, work safe – be safe.

Understanding Our Universe

"In answer to the question of why it happened, I offer the modest proposal that our Universe is simply one of those things which happen from time to time."

Edward P. Tryon

CONTINUING EDUCATION



APHL (Association of Public Health Laboratories) Parasitology Teleconferences

March 25, 2008 "Updates in Laboratory Diagnosis of Chagas Disease in the US"

September 30, 2008 "Trends in Laboratory Diagnosis of Leishmaniasis"

December 16, 2008 "Updates in the Diagnostic Detection of Free-Living Amoeba"

Registration deadline is two days before the conference. Register by phone at 240.485.2727 or online at http://www.nltn.org/instructions.htm

Clinical and Laboratory Standards Institute (CLSI)

K2Q "The Key to Quality" is an instructional binder and CD-ROM. The training is based on the 12 Quality System Essentials and aligned with the International Organization for Standardization (ISO) quality management standards. Visit their website at www.clsi.org.

Book

The Memory Jogger II for Laboratory Operations. You can order this small, inexpensive book at www.goalqpc.com.

Ponderables:
What disease did "cured" ham actually have?